REMARKS

The Office Action mailed June 3, 2009 has been received and reviewed. Each of claims 1, 7-11, 13, 14, 17, 18 and 21-24 stands rejected. Claim 1 has been amended herein. Care has been exercised to introduce no new subject matter. Reconsideration of the above-identified application in view of the above amendments and the following remarks is respectfully requested.

Rejections based on 35 U.S.C. § 102

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdeggal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 2 USPQ 2d 1913, 1920 (Fed. Cir. 1989). *See also* MPEP § 2131.

Claims 1, 7-9, 11, 13, 14, 17, 18 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Targan et al. (U.S. Patent No. 5,750,355, hereinafter Targan). As Targan fails to describe, either expressly or inherently, each and every element recited in the claims, Applicants respectfully traverse this rejection, hereinafter set forth.

Independent Claim 1

Independent claim 1 is directed to a method for diagnosing ulcerative colitis. The method comprises testing a *fecal sample* for elevated levels of anti-neutrophil cytoplasmic antibodies (ANCA) and diagnosing the person with elevated levels of ANCA in the fecal sample with ulcerative colitis (emphasis added).

In contrast to the invention of claim 1, Targan teaches a method of measuring the presence or absence of perinuclear anti-neutrophil cytoplasmic antibodies (ANCA) of ulcerative colitis and primary sclerosing cholangitis in a sample, where the sample is obtained from whole blood, plasma or serum. (Targan, col. 3, 65-68). Targan neither teaches nor suggests determining whether ANCA is present in a fecal sample. It does not disclose that ANCA may be in the feces of humans or that ANCA can cross through the intestinal wall from the serum and be contained in feces. Further, Targan does not describe that ANCA can cross the intestinal wall in an amount that could be measured to diagnose ulcerative colitis. Instead, in its examples, Targan only refers to the presence of ANCA in blood, serum, and sera. *See, e.g.*, Targan, Ex. I, II, V, IX, X, XI, and XII. As such, it does not teach or disclose determining whether ANCA is present in a fecal sample.

Therefore, it is respectfully submitted that Targan fails to describe, either expressly or inherently, each and every element of independent claim 1. Accordingly, claim 1 is not anticipated by Targan and withdrawal of the 35 U.S.C. § 102(b) rejection of the claim is respectfully requested. Claim 1 is believed to be in condition for allowance and such favorable action is respectfully requested

Claims 7-10 depend from independent claim 1. Accordingly, these claims are believed to be in condition for allowance for at least the above-cited reasons. Withdrawal of the 35 U.S.C. § 102(b) rejection of claims 7-10 is respectfully requested.

Independent Claim 11

Independent claim 11 is directed toward a diagnostic assay for differentiating between ulcerative colitis and Crohn's disease by determining whether a fecal sample contains an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA).

Applicant respectfully submits that Targan fails to describe, expressly or inherently, every element of independent claim 11 for the same reasons as set out for independent claim 1. Specifically, Targan fails to describe the presence of ANCA in a fecal sample. Accordingly, claim 11 is not anticipated by Targan and withdrawal of the 35 U.S.C. § 102(b) rejection of this claim is respectfully requested. Claim 11 is believed to be in condition for allowance and such favorable action is respectfully requested.

Claims 13-14 depend from independent claim 11. Accordingly, these claims are believed to be in condition for allowance for at least the above-cited reasons. Withdrawal of the 35 U.S.C. § 102(b) rejection of claims 13-14 is respectfully submitted.

Independent Claim 17

Independent claim 17 describes a method for screening for ulcerative colitis in patients with inflammatory bowel disease (IBD) by determining whether anti-neutrophil cytoplasmic antibodies (ANCA) are present in fecal sample of a person with IBD. If ANCA are present in the fecal sample, then a diagnosis of ulcerative colitis can be made.

Applicant respectfully submits that Targan fails to describe, expressly or inherently, every element of independent claim 17 for the same reasons as set out for independent claims 1 and 11. Specifically, Targan fails to describe the presence of ANCA in a fecal sample. Accordingly, claim 17 is not anticipated by Targan and withdrawal of the 35 U.S.C. § 102(b) rejection of this claim is respectfully requested. Claim 17 is believed to be in condition for allowance and such favorable action is respectfully requested.

Claims 18, 21-23 depend from independent claim 17. Accordingly, these claims are believed to be in condition for allowance for at least the above-cited reasons. Withdrawal of the 35 U.S.C. § 102(b) rejection of claims 18, 21-23 is respectfully submitted.

Rejections based on 35 U.S.C. § 103

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The Supreme Court in *Graham v. John Deere* counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in *Graham* and to provide some reason, or suggestions or motivations found either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art reference or to combine prior art reference teachings to produce the claimed invention. *See, In re Bergel,* 292 F. 2d 955, 956-57 (C.C.P.A. 1961). Thus, in order "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." *See* MPEP § 2143. Recently, the Supreme Court elaborated, "it will often be necessary [for the Office] to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in

the art," all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent application. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007).

Claims 10 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Targan as applied to claims 1 and 17 above, and further in view of Middeldorp et al. (U.S. Publication No. 2002/0169286, hereinafter Middeldorp).

Claim 10 is dependent from independent claim 1, which includes limitations not taught or suggested by Targan as described hereinabove. The addition of Middeldorp does not cure these deficiencies. Middeldorp teaches using a optical density of 450 nm for the detection of IgG complex of human samples under ELISA. Middeldorp does not cure the deficiencies of Targan and does not teach testing a fecal sample for elevated levels of ANCA and diagnosing that person with ulcerative colitis. As such, claim 10 is patentable over the Targan and Middeldorp references, and Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of claim 10.

Claim 24 is dependent from independent claim 17, which includes limitations not taught or suggested by Targan as described hereinabove. The addition of Middeldorp does not cure these deficiencies. As such, claim 24 is patentable over the Targan and Middeldorp references, and Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of claim 24.

CONCLUSION

For at least the reasons stated above, claims 1, 7-11, 13-14, 17-18 and 21-24 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or alindsey@shb.com (such communication via email is herein expressly granted) – to resolve the same.

Submitted herewith is a Request for One-Month Extension of Time along with the appropriate fee. It is believed that no additional fee is due, however, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number TLAB.100294.

Respectfully submitted,

/ASHLEY N. LINDSEY/

Ashley N. Lindsey
Reg. No. 64819

JMG/ARH/tq
SHOOK, HARDY & BACON L.L.P.
2555 Grand Blvd.
Kansas City, MO 64108-2613
816-474-6550